



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35
Public Health Service

SEP 21 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Ref:OC:I1-1867

via FEDERAL EXPRESS

David Scifres, Ph.D.
President & Chief Executive Officer
SDL, Incorporated
90 Rose Orchard Way
San Jose, California 95134

Dear Dr. Scifres:

This letter is written to advise you of items of noncompliance with the Federal performance standard for laser products encountered during the inspection performed by Francis Eng and Gary Zaharek, Electro-Optic Specialists, Pacific Region on April 13 and 14, 2000, of your Diode Laser System models FL-10, FL-20, and FD-25.

1. 21 CFR 1040.10(f)(4). The key could be removed from key control of the model FD-25 diode laser system while the key switch was in the "On" position. Further, based on a telephone discussion with Mr. Minh Trantien, Manager Environmental Health and Safety on August 29, 2000, forty of the model FD-25 Diode Laser Systems were shipped into commerce and another 289 model FL-10 and four model FL-20 Diode Laser Systems had this specific noncompliance and were shipped into commerce.
2. 21 CFR 1040.10(g)(7). The models FL-10, FL-20, and FD-25 diode laser systems failed to have a defeatably interlocked protective housing label affixed to the portion of the protective housing which is designed to be removed during operation, maintenance or service.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
 - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
 - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following failure to comply with the regulations regarding reports and record keeping were observed:

21 CFR 1002.30(a)(1)&(2). There were no test procedures to indicate the correct placement of the labels required by 21 CFR 1040.10(g) for the models FL-10 and FD-25 diode laser Systems. Further, the final

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test records for the FL-10, FL-20, and FD-25 diode laser systems failed to specify a specific test for the adequacy of the key control and the emission indicator delay.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch (HFR-PA140), San Francisco District Office, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda California 94502. If you have further questions on these requirements, please contact Manuel G. Karos of the Electronic Products Branch at (301) 594-4654 ext. 149.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Larry D. Spears for". The signature is written in a cursive, flowing style.

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health